

What is claimed is:

1) A method for delivering a pharmaceutical agent through a membrane, wherein the method comprises applying to said membrane a composition comprising:

- a) anionic phospholipids;
- b) a safe and effective amount of the pharmaceutical agent contained within the phospholipids; and
- c) a fusogenic protein or polypeptide derived from prosaposin

5 in a pharmaceutically acceptable carrier, wherein the concentration of the fusogenic protein or polypeptide is of a sufficient amount to deliver the pharmaceutical agent through the membrane.

10 2) The method of claim 2 wherein the concentration of phospholipids are in at least a 10-fold excess, by weight, to that of the fusogenic protein or polypeptide.

3) The method of claim 2 wherein the pH of the composition is between about 5.5 and 2.

4) The method of claim 3 wherein the anionic phospholipid is an anionic liposome.

5) The method of claim 4 wherein the fusogenic protein or polypeptide is associated with the liposome through an electrostatic and hydrophobic interaction.

6) The method of claim 5 wherein the membrane is selected from the group consisting of dermal and mucosal membranes.

7) The method of claim [REDACTED] wherein the fusogenic protein or polypeptide is selected from the group consisting of saposin A, saposin C, polypeptide analogs, derivatives, homologues, fragments of saposin A and saposin C, and mixtures thereof.

8) The method of claim 6 wherein the fusogenic protein or polypeptide is saposin C.

9) The method of claim 6 wherein the fusogenic protein or polypeptide is SEQ. ID. NO. 1.

10) The method of claim 6 wherein the fusogenic protein or polypeptide is SEQ. ID. NO. 2.

11) The method of claim 6 wherein the fusogenic protein or polypeptide is of the formula  
$$\text{h-u-Cys-Glu-h-Cys-Glu-h-h-h-Lys-Glu-h-u-Lys-h-h-Asp-Asn-Asn-Lys-u-Glu-}$$
$$\text{Lys-Glu-h-h-Asp-h-h-Asp-Lys-h-Cys-u-Lys-h-h,}$$
where h = hydrophobic amino acids, including, Val, Leu, Ile, Met, Pro, Phe, and Ala; and u = uncharged polar amino acids, including, Thr, Ser, Tyr, Gly, Gln, and Asn.

12) The method of claim 7 wherein administration of the composition is via a transdermal patch.

13) The method of claim 7 wherein the composition is administered either enterally or topically.

14) A method for delivering a pharmaceutical agent through either a dermal or mucosal membrane, wherein the method comprises the administration to said membrane of a composition comprising:

5 a) anionic liposo

b) a safe and effective amount of the pharmaceutical agent contained within the  
liposomes; and

c) saposin C;

in a pharmaceutically acceptable carrier, wherein the concentration of the liposomes are  
of a sufficient amount to deliver a safe and effective amount of the pharmaceutical agent  
10 through the membrane, the pH of the composition is between about 5.5 and 2, and the  
saposin C is associated with the surface of the liposome through an electrostatic and  
hydrophobic interaction.

15) The method of claim 14 wherein the concentration of the liposomes is in at least a 10-fold  
excess, by weight, to that of saposin C.

16) A therapeutic phospholipid composition comprising:

a) an anionic phospholipid;

b) a safe and effective amount of the pharmaceutical agent contained within the  
phospholipids; and

c) a fusogenic protein or polypeptide derived from prosaposin;

in a pharmaceutically acceptable carrier, wherein the concentration of the fusogenic  
protein or polypeptide is present in a sufficient concentration to deliver the  
pharmaceutical agent through a biological membrane and the fusogenic protein or  
polypeptide is associated with the phospholipid through an electrostatic and hydrophobic  
10 interaction.

17) The phospholipid composition of claim 16 wherein the concentration of phospholipids is  
in at least a 10-fold excess, by weight, to that of the fusogenic protein or polypeptide.

18) The phospholipid composition of claim 17 wherein the pH of the composition is between about 5.5 and 2.

19) The phospholipid composition of claim 18 wherein the anionic phospholipid is an anionic liposome.

20) The phospholipid composition of claim 19 wherein the biological membrane is selected from the group consisting of dermal and mucosal membranes.

21) The phospholipid composition of claim 20 wherein the fusogenic protein or polypeptide is selected from the group consisting of saposin A, saposin C, polypeptide analogs, derivatives, homologues, fragments of saposin A and saposin C, and mixtures thereof.

22) The phospholipid composition of claim 20 wherein the fusogenic protein or polypeptide is saposin C.

23) The phospholipid composition of claim 20 wherein the fusogenic protein or polypeptide is SEQ. ID. NO. 1.

24) The phospholipid composition of claim 20 wherein the fusogenic protein or polypeptide is SEQ. ID. NO. 2.

25) The phospholipid composition of claim 20 wherein the fusogenic protein or polypeptide is of the formula

h h-u-Cys-Glu-Lys-Glu-h-h-h-Lys-Glu-h-u-Lys-h-h-Asn-Asn-Lys-u-Glu-Lys-Glu-h-h-Asp-h-h-Asp-Lys-h-Cys-u-Lys-h-h,

5 where h = hydrophobic amino acids, including, Val, Leu, Ile, Met, Pro, Phe, and Ala; and u = uncharged polar amino acids, including, Thr, Ser, Tyr, Gly, Gln, and Asn.

26) The phospholipid composition of claim 21 wherein the composition is formulated as part of a transdermal patch.

27) The phospholipid composition of claim 21 wherein the composition is formulated for enteral or topical administration.

28) A therapeutic phospholipid composition used to deliver a pharmaceutical agent through either a dermal or mucosal membrane, wherein the composition comprises:

- a) anionic liposomes;
- b) a safe and effective amount of the pharmaceutical agent contained within the liposomes; and
- c) a fusogenic protein or polypeptide selected from the group consisting of saposin C, polypeptide analogs, derivatives, homologues, fragments of saposin C, and mixtures thereof;

in a pharmaceutically acceptable carrier where the pH of the composition is between 10 about 5.5 and 2, wherein the concentration of the fusogenic protein or polypeptide is of a sufficient amount to deliver the pharmaceutical agent through a biological membrane and the fusogenic protein or polypeptide is associated with the surface of the liposome through an electrostatic and hydrophobic interaction.

29) The phospholipid composition of claim 28 wherein the concentration of the liposomes is in at least a 10-fold excess, by weight, to that of saposin C.

5

30) A composition comprising a safe and effective amount of a pharmaceutical agent contained in an anionic liposome, which is associated with a prosaposin-derived fusogenic protein or polypeptide via an electrostatic and hydrophobic interaction, wherein the concentration of the fusogenic protein or polypeptide is of a sufficient amount to deliver the pharmaceutical agent through a biological membrane, the composition contained in a pharmaceutically acceptable carrier, wherein the pH of the composition is between about 5.5 and 2.

CONFIDENTIAL

31) The composition of claim 30 wherein the concentration of liposomes is in at least a 10-fold excess, by weight, to that of the fusogenic protein or polypeptide.

32) The composition of claim 31 wherein the biological membrane is selected from the group consisting of dermal and mucosal membranes.

33) The composition of claim 32 wherein the fusogenic protein or polypeptide is selected from the group consisting of saposin A, saposin C, polypeptide analogs, derivatives, homologues, fragments of saposin A and saposin C, and mixtures thereof.

34) The phospholipid composition of claim 31 wherein the fusogenic protein or polypeptide is saposin C.

35) The composition of claim 31 wherein the fusogenic protein or polypeptide is SEQ.ID.NO. 1.

36) The composition of claim 31 wherein the fusogenic protein or polypeptide is SEQ.ID.NO. 2.

37) The composition of claim 31 wherein the fusogenic protein or polypeptide is of the formula

h-u-Cys-Glu-h-Cys-Glu-h-h-h-Lys-Glu-h-u-Lys-h-h-Asp-Asn-Asn-Lys-u-Glu-Lys-Glu-h-h-Asp-h-h-Asp-Lys-h-Cys-u-Lys-h-h,

5 where h = hydrophobic amino acids, including, Val, Leu, Ile, Met, Pro, Phe, and Ala; and

u = uncharged polar amino acids, including, Thr, Ser, Tyr, Gly, Gln, and Asn.

38) A phospholipid composition used to deliver a pharmaceutical agent through either a dermal or mucosal membrane, wherein the composition comprises:

- a) anionic liposomes;
- b) a safe and effective amount of the pharmaceutical agent contained within the liposomes; and
- c) saposin C;

in a pharmaceutically acceptable carrier, wherein the pH of the composition is between about 5.5 and 2, the concentration of the saposin C is of a sufficient amount to deliver the pharmaceutical agent through the membrane and the saposin C is associated with the 10 surface of the liposome through an electrostatic and hydrophobic interaction.

39) The phospholipid composition of claim 38 wherein the concentration of the liposome is in at least a 10-fold excess, by weight, to that of saposin C.

40) The polypeptide of SEQ. ID. NO. 1.

41) The polypeptide of SEQ. ID. NO. 2.

42) A compound of the formula

h-u-Cys-Glu-h-Cys-Glu-h-h-h-Lys-Glu-h-u-Lys-h-h-Asp-Asn-Asn-Lys-u-Glu-Lys-Glu-h-h-Asp-h-h-Asp-Lys-h-Cys-u-Lys-h-h,

where h = hydrophobic amino acids, including, Val, Leu, Ile, Met, Pro, Phe, and Ala;

5 and u = uncharged polar amino acids, including, Thr, Ser, Tyr, Gly, Gln, and Asn.

43) A method for treating Gauchers Disease wherein the method comprises the administration of a composition comprising:

- a) anionic liposomes;
- b) a safe and effective amount of acid beta-glucosidase contained within the liposomes; and
- c) saposin C;

in a pharmaceutically acceptable carrier, wherein the pH of the composition between about 5.5 and 2, the concentration of the saposin C is of a sufficient amount to deliver the pharmaceutical agent through the membrane and the saposin C is associated with the 10 surface of the liposome through an electrostatic and hydrophobic interaction.

44) The method of claim 43 wherein the concentration of the liposome is in at least a 10-fold excess, by weight, to that of saposin C.